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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KIM, YOUNG J	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 01/27/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application N .	Applicant(s)	
	09/233,218	CAJACOB ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE f this c mmunication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 10-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 10-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This Office Action responds the Amendment received on November 12, 2002 (Paper No. 27).

Preliminary Remark – Amendment to the specification

The Office acknowledges Applicants' amendment to the specification to correct obvious typographical error. Applicants are, however, advised that the SEQ ID Numbers which were amended to be excluded are drawn to "putative" soybean or maize glutamyl t-RNA reductase and protochlorophyllide reductase enzymes.

Claims 1 and 10-23 are under prosecution.

Claim Rejections - 35 USC § 101 – 112 first Enablement

The rejection of claims 11-21 under 35 U.S.C. 101 for lacking patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility, in the Office Action mailed on August 14, 2002 is withdrawn in view of careful reconsideration and in view of the arguments presented in the Amendment received on November 12, 2002.

Rejections – New Grounds, Necessitated by Amendment

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1, 2, and 10-21 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable

one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, in the Office Action mailed on August 14, 2002 is maintained for the reasons of record. New claims 22 and 23 are also rejected under the same statute (these claims necessitated by amendment).

Applicants' argument received on November 12, 2002 have been fully considered but they are not found persuasive.

Claims 1, 10, 22, and 23 are drawn to a substantially purified nucleic acid molecule that encodes a maize glutamyl-tRNA reductase enzyme or a fragment thereof, wherein said nucleic acid comprises a nucleic acid sequence selected from the group consisting of SEQ ID Numbers: 586, 590, 594, 596, 597, 599, 600, 601, 604, 605 and complements thereof.

Claims 11-21 are drawn to a substantially purified nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of the same above SEQ ID Numbers.

Applicants argue that the Office has not met the evidentiary burden to impose an enablement rejection for failure to enable one of skill to use the invention. Applicants state that, a specification that discloses how to use a claimed invention must be taken as in compliance with the enabling requirement of the first paragraph of 112 unless there is reason to doubt the objective truth of the statement contained therein (page 9, argument). Because the present specification teaches how to use the claimed invention (i.e., detect polymorphisms, probes, etc), the Office failed to provide specific evidence supporting the rejection, nor any specific explanation of why the specification allegedly fails to enable these uses, citing *Ex parte Lemark,* 210 USPQ 306, 307 (Bd. App. 1981) wherein the board stated that "pure conjecture" does not substantiate rejection for lack of enablement.

Preliminarily, 210 USPQ 307 is not an *Ex parte Lemark* case, but rather *Warnaco Inc. v. Adventure Knits, inc.*, which is discusses trademark issues and not patentability issues.

Applicants are advised that the rejection under 35 U.S.C. 101 for lacking patentable utility was solely based on the Applicants' asserted utility of the claimed nucleic acids encoding glutamyl-tRNA reductase enzyme and thus, the enablement argument will be drawn to whether or not the claimed nucleic acids do in fact encode a functional glutamyl-tRNA reductase.

Applicants contend that the reasons set forth by the Office for holding the claimed nucleic acids non-enabling is based on "pure conjecture." However, the Office did not base the rejection based on a pure conjecture. The Office provided a document which demonstrates the **state of the prior** art in assigning protein functions purely based on its percent similarity to a known protein - that it is unpredictable. The specification does not give anymore information other than the fact that the claimed nucleic acids exhibit 60-70% homology to known glutamyl-tRNA reductase enzymes across species such as barely, *Arabidopsis* and cucumbers; 82%-89% similarity with a maize glutamyl-tRNA reductase (Glu TR). The specification does not identify any of the functional conserved domains shared among the species of the Glu TR nor how the claimed nucleic acid (and the encoded protein) would share these conserved domains. Not only does the specification lack complete open reading frame of the claimed nucleic acids, but it also lacks information on which of the disclosed sequences are drawn to the functional domains of the Glu TR enzyme. The only information that the specification does contain is the fact that the claimed nucleic acids share "sequence" homology to known proteins among Glu TR enzymes of known species.

Applicants also state that the specification discloses that purified barely Glu TR has a molecular weight of 270 kD with a monomeric subunit size of 54 kD, but **fails** to disclose whether any of the claimed nucleic acids share this subunits (emphasis added).

With respect to the Applicants' argument drawn to the disclosure of Iyers et al., such argument is not persuasive because the reference discloses the state of the prior art, that is, assigning protein functions purely based on homology. The reference clearly demonstrates that such assumption is premature.

Iyers et al. state that:

"Despite these achievements [in computational predictions], detection and interpretation of relationships between homologous proteins that have limited sequence similarity remains a **major challenge.** Such studies typically require a case-by-case approach that is guided by a detailed understanding of protein sequence-structure patterns..."

The present specification does not disclose any of structural information of the claimed nucleic acids with respect to a known Glu TR enzyme. Although the artisans clearly state that even with such disclosures computational assignment of protein function is a "major challenge," Applicants contend that a simple sequence homology comparison is enough for assignment of functions.

Iyers et al. continue state that, "[t]he negative feedback from experiments that failed to confirm a computational prediction is potentially even more important, because it could result in revision and refinement of the computational methods," demonstrating presence of unpredictability computational assignment of protein functions.

Since the instant specification or the evidence of record reasonably would guide a skilled practitioner to use the claimed nucleic acids for encoding functional maize glutamyl-tRNA reductase based on the reasons set forth above, the instant claims are rejected for failing to enable a skilled practitioner to make and/or use the claimed nucleic acids as Glu TR enyzme.

The rejection of claims 1, 10, and 11-21 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the invention was filed, had possession of the claimed invention, in the Office Action mailed on August 14, 2002 is maintained for the reasons of record. New claim 22 is also rejected under the same statute (these claims necessitated by amendment).

The issue is whether Applicants were in possession of the genus being claimed. This genus is not restricted to any particular disclosed subgenus or species, such as vectors comprising any of SEQ ID Numbers 586, 590, 594, 596, 597, 599, 600, 601, 604, 605 and complements thereof as an insert. The only nucleic acid molecules described by complete structure are those consisting of any of SEQ ID Numbers 586, 590, 594, 596, 597, 599, 600, 601, 604, and 605. The only nucleic acid molecules comprising any of SEQ ID NOS: 586, 590, 594, 596, 597, 599, 600, 601, 604, and 605 described in the specification by other characteristics are generic vectors comprising any of SEQ ID Numbers 586, 590, 594, 596, 597, 599, 600, 601, 604, and 605. While it is acknowledged that Applicants need not describe "every nuance" of the claimed invention, the written description must bear a reasonable correlation to that which is claimed. The disclosed subgenus and species embraced by the claims are not representative of

the entire genus being claimed. The genus of nucleic acid molecules being claimed embraces any and every type of nucleic acid molecule that comprises any of SEQ ID Numbers 586, 590, 594, 596, 597, 599, 600, 601, 604, and 605, and additional sequences of any size and sequence, not just vector backbones. Clearly, at the time of filing, Applicants were not in possession of genomic materials that contain the common EST fragment, **which are embraced** by the open-ended claims. The specification does not disclose what characteristics these additional sequences may or may not have that are consistent with the operability of the nucleic acid molecules as probes or primers for detection of SEQ ID Numbers 586, 590, 594, 596, 597, 599, 600, 601, 604, and 605 in a target sequence, and all disclosed uses for the claimed nucleic acid molecules are fundamentally as probes or primers, at least in some aspect. The specification does not disclose encoding sequences or open reading frames (ORFs).

With respect to full length mRNAs, cDNAs and genomic sequences, one skilled in the art would reasonably conclude that the claims embrace these nucleic acid molecules, and the specification provides no physical (i.e. structural) characteristics of these molecules to distinguish them from other nucleic acid molecules comprising any of SEQ ID Numbers 586, 590, 594, 596, 597, 599, 600, 601, 604, and 605, and no other indication that would suggest Applicants possessed them. This particular subgenus embraced by the claims has a disclosed potential utility not possessed by those members of the claimed genus useful only in hybridization. Full length mRNAs, cDNAs and genomic sequences (genes) would encode the corresponding protein(s).

A fundamental issue here is specific to the very narrow class of product that is nucleic acid molecules. The basic question upon which Applicants and the Examiner disagree is

whether the disclosure of a partial sequence of otherwise uncharacterized nucleic acid molecules that may encode a corresponding protein is sufficient to establish possession of a broad genus based solely on the description of the partial sequence, where the broad genus embraces the uncharacterized nucleic acid molecules by default. The subgenus of uncharacterized nucleic acid molecules that encode any corresponding protein is explicitly alluded to in the specification, and disclosed as possessing an additional use *not* possessed by any other members of the broad genus being claimed, i.e. encoding the protein. The specification fails to provide any structural or functional characteristic for these desired nucleic acid molecules, which encode the protein, that would distinguish them from the other members of the genus, which simply comprise any of SEQ ID Numbers 586, 590, 594, 596, 597, 599, 600, 601, 604, and 605 as the sole distinguishing feature. As stated in *University of California v. Eli Lilly and Co.* at page 1404:

> An adequate written description of a DNA ... "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

That Applicants' claims embrace nucleic acid molecules that encode a corresponding protein, whatever it may be, is clearly evident from the claim language chosen. The Court in *University of California v. Eli Lilly and Co.*, at page 1405, further noted regarding generic claims:

> A written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other materials. *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe* , 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not

necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . .").

In the instant case, the only species specifically enumerated are the nucleic acid molecules of SEQ ID Numbers 586, 590, 594, 596, 597, 599, 600, 601, 604, and 605 themselves. The specific embodiments that in addition to SEQ ID NO: 586, 590, 594, 596, 597, 599, 600, 601, 604, and 605 include nucleic acids that will allow the corresponding protein to be encoded cannot be predicted without the coding sequence itself. This coding sequence has not been disclosed. Clearly, the specification would not show one skilled in the art that these desired subcombinations were possessed by Applicants, and thus the embracing genus was also not possessed.

Claim Rejections - 35 USC § 102

The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Baysdorfer (Accession No. W21756, GenBank, May 1996), in the Office Action mailed on August 14, 2002 is withdrawn in view of the Amendment received on November 12, 2002, amending the claim.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

1/21/03

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

1/23/03